

REMARKS

Claims 1-4, 9, 10, 12, 17-22 and 24 have been rejected under 35 U.S.C. 102(b) as being anticipated by Lawin et al. (U.S. Patent No. 5,792,478). Reconsideration of these claims is respectfully requested.

Lawin et al. disclose an invention that consists of an injectable composition that is a combination of a plurality of small, smooth-surfaced particles that are carried in a lubricative fluid or gel that is preferably comprised of a biologically compatible, lubricous solution, suspension, other fluid or gel. Col. 3, lines 40-44. The compositions may be injected into the tissue of the anal canal, wherein the selected site may be, for example, the internal or external anal sphincter tissue. The resulting bulking or augmentation of the tissue will restrict the size of the sphincter or anal passage and thus assist in overcoming fecal incontinence. Col. 6, lines 22-27.

Amended Claim 1 is patentable over Lawin et al. by calling for a method for treating fecal incontinence in a body of a mammal having a rectum formed by a rectal wall extending to an anus wherein the rectal wall includes a sphincter muscle surrounding the anus comprising the steps of introducing a biocompatible prepolymer into the rectal wall in the vicinity of the anus and polymerizing the biocompatible prepolymer in situ to form a nonbiodegradable solid in the rectal wall. As noted above, Lawin et al. does not disclose a method for introducing a biocompatible prepolymer into the rectal wall, let alone polymerizing the biocompatible prepolymer in situ to form a nonbiodegradable solid in the rectal wall.

Claims 2-5, 9-10 and 12-16 and new Claim 26 depend from Claim 1 and are patentable for the same reasons as Claim 1 and by reason of the additional limitations called for therein. Claims 6-8 and 11 have been cancelled.

Amended Claim 17 is patentable by calling for a method for treating fecal incontinence in a body having an anal sphincter comprising the step of polymerizing a biocompatible prepolymer in situ to form at least one nonbiodegradable implant in said sphincter. As noted above, Lawin et al. does not disclose polymerizing a biocompatible prepolymer in situ to form at least one nonbiodegradable implant in an anal sphincter.

Claims 18-21 depend from Claim 17 and are patentable for the same reasons as Claim 17 and by reason of the additional limitations called for therein.

Claims 1-5, 9, 10 and 12-21 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-28 of U.S. Patent No. 6,553,717 and over Claims 1-30 of U.S. Patent No. 6,251,063. Claims 1-5, 9, 10 and 12-24 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-23 of U.S. Patent No. 6,595,910. In each instance, it is stated that although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are an obvious broadening of the scope of the patented claims.

With respect to the '717 Patent, Claims 1-16 thereof are limited to precipitating from at least one nonaqueous solution a nonbiodegradable solid, Claims 17-22 thereof are limited to precipitating a biocompatible polymer from a solution of a biocompatible polymer and a biocompatible solvent and Claims 23-28 thereof are limited to precipitating a biocompatible polymer from at least one nonaqueous solution. Claims 1-5, 9, 10 and 12-21 herein are not limited to precipitating from a solution but instead are patentably distinct from the claims of the '717 Patent by being limited to polymerizing a biocompatible prepolymer in situ to form a nonbiodegradable solid or at least one nonbiodegradable implant. Nor are the claims herein an obvious broadening of the claims of the '717 Patent. In view of the foregoing, the nonstatutory obviousness-type double patenting rejection with respect to the '717 Patent should be withdrawn.

With respect to the '063 Patent, Claims 1-21 and Claims 22-27 thereof are limited to introducing at least one nonaqueous solution into muscle and forming a nonbiodegradable solid or at least one implant from the solution, while Claims 28-30 thereof are limited to introducing a solution of a biocompatible polymer and a biocompatible solvent into a wall and precipitating the biocompatible polymer from the solution. Claims 1-5, 9, 10 and 12-21 herein are not limited to introducing a solution and forming or precipitating from the solution but instead are patentably distinct from the claims of the '063 Patent by being limited to polymerizing a biocompatible prepolymer in situ to form a nonbiodegradable solid or at least one nonbiodegradable implant. Nor are the claims herein an obvious broadening of the claims of the '063 Patent. In view of the

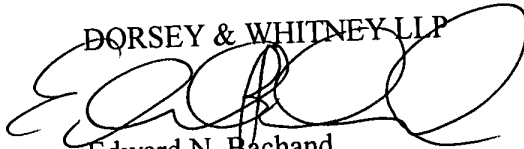
foregoing, the nonstatutory obviousness-type double patenting rejection with respect to the '063 Patent should be withdrawn.

With respect to the '910 Patent, Claims 1-15 thereof are limited to introducing at least one nonaqueous solution into a wall and forming a nonbiodegradable solid from the solution, Claims 16-19 thereof are limited to bridging a damaged portion of a sphincter with an implant, while independent Claims 20-23 thereof are limited to forming a rod-like implant in a rectal wall. Claims 1-5, 9, 10 and 12-24 herein are not limited to introducing a solution and forming or precipitating from the solution, bridging a damaged portion of a sphincter or forming a rod-like implant in a rectal wall, but instead are patentably distinct from the claims of the '910 Patent by being limited to polymerizing a biocompatible prepolymer in situ to form a nonbiodegradable solid or at least one nonbiodegradable implant. Nor are the claims herein an obvious broadening of the claims of the '910 Patent. In view of the foregoing, the nonstatutory obviousness-type double patenting rejection with respect to the '717 Patent should be withdrawn.

In view of the foregoing, it is respectfully submitted that the claims of record are allowable and that the application should be passed to issue. Should the Examiner believe that the application is not in a condition for allowance and that a telephone interview would help further prosecution of this case, the Examiner is requested to contact the undersigned attorney at the phone number below.

Respectfully submitted,

DORSEY & WHITNEY LLP


Edward N. Bachand
Reg. No. 37,085

Customer No. 32,940
Suite 1000
555 California Street
San Francisco, CA 94104-1513
Telephone No.: (650) 857-1717
Facsimile No.: (650) 857-1288

4827-7863-3985\1